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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/807,837 | 03/24/2004 | Wenfeng Xu | 03-02 | 4419 |

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11/26/2008

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| EXAMINER |
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STOICA, ELLY GERALD

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| ART UNIT | PAPER NUMBER |
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1647

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11/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 10/807,837 | Applicant(s) XU ET AL. | |
| | Examiner ELLY-GERALD STOICA | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/20/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

1. In the amendment filed on 08/20/2008 Applicant cancelled claims 15-22 and 74-80. Thus, claims 55-60 are pending and are currently examined.

Withdrawn claim rejections

Double Patenting

2. The provisional rejection of claims 15-22 and 55-60 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-22 and 55-60 of copending Application No. 11/256499 and Application No. 11/350375 is withdrawn in view of the amendments to the claims of the instant Application as well as the co-pending Applications.

Maintained claim rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 55-57 and 59 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Busfield (US 2002/0164689A1) in view of Hopp et al. (Hopp, TP and Woods, KR, Proc. Natl. Acad. Sci. USA: 78, 3824-28, 1981) and in further view of Lok et al. (U.S. Pat. No. 5,965,704) for the reasons of record.

On pages 4-5 of the Remarks Applicant argues that Busfield cannot be combined with Hopp et al. because Busfield, by teaching antigenic peptides comprising at least 8 amino acids, teaches away from Hopp et al.

The arguments were carefully considered but not found persuasive because, as iterated in the previous Office actions, Applicants are arguing the references individually rather than in the combination in which they were cited. It is not required that the teachings of Busfield be used only for the preferred embodiments. The entirety of the disclosure is evaluated and applied as appropriate. In this case, Busfield was cited to teach an antibody that selectively binds to an isolated polypeptide consisting of a fragment of a polypeptide comprising the amino acids sequence of SEQ. ID. NO: 2 or 12, wherein the fragment comprises at least 15 contiguous amino acids of SEQ. ID. NO: 2 OR 12 (US 2002/0164689A1 § [0169]-(0181]). SEQ. ID. NO: 2 from Busfield is identical to SEQ. ID. NO: 2 of the instant application and contains sequence SEQ. ID. NO: 3 from the instant application. Although the sequence PEDPSD is implicitly present, Busfield does not teach making an antibody specifically against the PEDPSD hexapeptide.

Hopp et al. teach that the best antigenicity is obtained by using **hexapeptides** (p.3826-Table 3) and especially peptides rich in P, E and D (p.3826-Table 2). A person of ordinary skill in the art would have easily been motivated to take the teachings of Busfield under advisement since the art was recommending **hexapeptides rich in P, E and D** for excellent results. The fact that Busfield used octapeptides cannot be

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construed as teaching against the use of hexapeptides. A person of ordinary skill in the art would have been motivated to use the hexapeptide PEDPSD from the amino terminus of the polypeptide of Busfield, because of Hopp's teaching that hexapeptides rich in PE and D are especially desirable for the production of antibodies. A person of ordinary skill in the art is always motivated to pursue the known options within her or his technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

5. Claims 58 and 60 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Busfield (US 2002/0164689A1) in view of Hopp et al. (Hopp, TP and Woods, KR, Proc. Natl. Acad. Sci. USA: 78, 3824-28, 1981) and in further view of Lok et al. (US Patent 5,965,704.) and Gonzales et al. (U. S. Pat. No. 6,133,426) for the reasons of record.

On page 6 of the Remarks Applicant argues that, since the claims are dependent on an allegedly non-obvious independent claim (claim 55), the claims 58 and 60 are not obvious for reasons the same as for the above rejection..

The arguments were carefully considered but not found persuasive because as presented *supra*, claim 55 is obvious over Busfield in view of Hopp et al. Lok et al. provide the teaching and motivation to PEGylate the protein. Applicants have presented no arguments drawn specifically to the combination of Busfield, Hopp, Lok and Gonzalez. Consequently, the claims 58 and 60 remain obvious over the cited prior art.

Conclusion

6. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/
Primary Examiner, Art Unit 1647